K132904
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Ziehm Imaging GmbH | Donaustrasse 31 | 90451 Nuremberg | Germany

U.S. Food and Drug Administration
Center for Devices and Radiological Health
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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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Volume 002 – 510 (k) Summary

Oct 31, 2013

In accordance with 21 CFR §807.92 the following 510(k) summary information is provided:

Submitter Address:	Ziehm Imaging GmbH Donaustrasse 31 90451 Nuremberg Germany Phone: + 49.911.2172-219 Fax: +49.911.2172-390
Primary Contact Person / Agent:	Richard L. Westrich Director of Regulatory Affairs and Quality Assurance Ziehm Imaging, Inc. Phone: (407) 615-8560 Ext 140 Fax: (470) 615-8561
Secondary Contact Person:	Stefan Fiedler Director QM/RA Ziehm Imaging GmbH Phone: + 49.911. 2172-219 Fax: +49.911.2172-390
Device (Trade Name):	Ziehm Vision RFD
Common /Usual Names:	Mobile Fluoroscopic C-Arm

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Classification Product Code:	21CFR 892.1650
Classification Names:	Image-intensified fluoroscopic x-ray system
Device:	Interventional fluoroscopic x-ray system
Product Code:	OWB
Subsequent Classification(s) Product Code:	21CFR 892.1650
Classification Names:	Image-intensified fluoroscopic x-ray system
Device:	System, x-ray, fluoroscopic, image-intensified
Product Code:	JAA
Subsequent Classification(s) Product Code:	21CFR 892.1650
Classification Names:	image-intensified fluoroscopic x-ray system, mobile
Device:	Image-intensified fluoroscopic x-ray system.
Product Code:	OXO
Predicate Device:	K083545 Ziehm Vision RFD
General Description:	The ZIEHM VISION RFD employs X-rays as its imaging technology for visualizing human anatomy. The X-ray tube in the generator produces X-rays that are directed toward the patient under control of the user at the direction of a physician who determines the specific clinical procedure. The images from the system assist the physicians in visualizing the patient's anatomy. This visualization helps to localize regions of pathology and for surgical procedures. The device provides real-time visualization and image capture of in vivo surgical procedures and post-surgical outcomes. The Ziehm Vision RFD mobile fluoroscopy system is a flat panel detector (FD) fluoroscopic X-ray imaging system consisting of two mobile units: a Mobile Stand (C-Arm) and a Monitor Cart/Workstation. The Mobile Stand is comprised of a mono-block high voltage generator, X-ray control, and a C-Profile which is "C" shaped and supports the X-ray generator and the image receptor Flat Panel Detector (FD).

The proposed device will add motorized movement to three additional axes of the predicate device vertical motorized movement. This provides the user/operator the option to use manual or motorized linear and rotational movements of the C- Profile for positioning of the imaging components at various angles and distances with respect to the patient using a control interface, Vision Center, Remote Vision Center or remote Position Control Center.

The motorization of the three axes provides the user an alternative for visualizing anatomical structures using a selectable iso-centric location. With the freely selectable iso-center and distance control, any given anatomical structure can be safely visualized from different angles without having to re-adjust the C-arm. The iso-center is not restricted to orbital movements, but is held during angulations and vertical travel using the now available 4 motorized axes. The Distance Control surface detection integrated around the lower edge of the flat panel detects objects, such as patients. When the flat panel approaches an object, the device reduces speed, slowing the motorized movement. The movement stops immediately before entering a defined safety zone.

The Monitor Cart is a mobile platform that connects to the Mobile Stand by a cable, and which integrates the LCD flat panel display monitors, image processing user controls and image recording devices. Interfaces provided for optional peripheral devices such as external monitors, thermal video printers, injectors and image storage devices (USB, DVD) and DICOM Network interfaces.

Indications for Use: The ZIEHM VISION RFD is intended for use in providing medical imaging, using pulsed and continuous fluoroscopic digital imaging, as well as digital subtraction and cine image capture during diagnostic interventional and surgical procedures where intra-operative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional angiography, electrophysiology, pediatrics, endoscopic, urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room

procedures, and those procedures visualizing structures of the cervical, thoracic, and lumber regions of the spine and joint fractures of the upper and lower extremities, and where digital image data is required for computer aided surgery procedures, and whenever the clinician benefits from the high degree of geometric imaging accuracy, and where such fluoroscopic, cine and DSA imaging is required in and around high magnetic fields. The visualization of such anatomical structures assists the clinician in the clinical outcome. At the discretion of a physician, the device may be used for other imaging applications.

This device does not support direct radiographic film exposures and is not intended for use in performing mammography. The system is not intended for use near MRI systems.

Summary of Technological Characteristics:

The comparisons of the predicate device show the scientific and technology characteristics of the Ziehm Vision RFD are substantial equivalence to that of the predicate device.

Summary of Non-Clinical Test Data:

Ziehm Vision RFD is based on modifications to a cleared predicate device Ziehm Vision RFD (K083545); The Ziehm Vision RFD design changes were completed in accordance with Ziehm Imaging GmbH Quality Management System Design Controls and Engineering, standards compliance, and Verification and Validation testing were successfully conducted. Tests were performed on the Ziehm Vision RFD which demonstrated that the device is safe and effective, performs comparably to the predicate device, and is substantially equivalent to the predicate device. Tests included verification/validation testing to internal; functional specifications (including software) and non-clinical image comparisons involving flat panel display images taken with the new device and the predicate device. Documentation provided demonstrates compliance of the modified device Ziehm Vision RFD to all FDA requirements stated in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation tests to software requirements and software risk hazards.

Performance testing confirmed, that the Ziehm Vision RFD complies with 21 CFR 1020.30-32 Federal Performance

Standards for X-Ray Fluoroscopic equipment and with relevant voluntary safety standards for Electrical Safety and Electromagnetic Compatibility testing, specifically IEC standards listed in the table below. Together, the verification/validation activities successfully confirmed device requirements are fulfilled, system functionality is consistent with the user needs, intended uses, and the Ziehm Vision RFD device correctly performs as designed, and raises no new questions regarding either safety or effectiveness. Therefore, when compared to the predicate device the Ziehm Vision RFD supports a determination of substantial equivalence to the predicate device.

Compliance Standards:

FDA/CDRH From 3626 (5/11)	A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components.
21 CFR 1020.30-32	Federal Performance Standard for Diagnostic X-ray Systems.
MDD 93/42/EEC	Annex II of the Medical Devices Directive (MDD) 93/42/EEC
IEC 60601-1:2005	Medical Electrical Equipment, General Requirements for Safety. Edition 3.0, Date: 2005-12-15, Conformance Standard #5-4
IEC 60601-1-2: 2007	Medical Electrical Equipment, General Requirements for Safety, Electromagnetic Compatibility. Edition 3.0, Date: 2007-03-30, Conformance Standard #5-53
IEC 60601-1-3: 2008	Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray Equipment. Edition 2.0, Date: 2008-01-22, Conformance Standard #12-210
IEC 60601-2-43: 2010	Medical electrical equipment, Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures. Edition 2.0, Date: 2010-03-25, Conformance Standard #12-202
IEC 60601-2-54: 2009	Medical electrical equipment, Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy. Edition 1.0, Date: 2009-06-29, Conformance Standard #12-201

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IEC 60825-1: 2007	Safety of laser products, Equipment Safety, requirements, and user guide Edition 2.0, Date: 2007-03-30 Conformance Standard #12-220
ISO 14971: 2007	Application of risk management to medical devices. Edition 2.0, Date: 2007-03-01, Conformance Standard #5-40

Conclusion Ziehm Imaging GmbH considers the modified Ziehm Vision RFD to be as safe, as effective, and performs substantially equivalent to the predicate device Ziehm Vision RFD (K083545) and in accordance with its labeling.

End of 510(k) Summary

Richard L. Westrich
Official Agent and Correspondent for Ziehm Imaging GmbH.
Ziehm Imaging Inc,
6280 Hazeltine National Drive
Orlando, Fl. 32822

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 5, 2013

Ziehm Imaging GmbH
% Mr. Richard L. Westrich
Director of Regulatory Affairs and Quality Assurance
Ziehm Imaging, Inc.
6280 Hazeltine National Drive
ORLANDO FL 32822

Re: K132904
Trade/Device Name: Ziehm vision rfd
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, OXO, JAA
Dated: November 4, 2013
Received: November 8, 2013

Dear Mr. Westrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

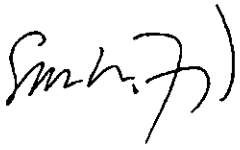
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K132904

Device Name: ZIEHM VISION RFD

Indications for Use:

The ZIEHM VISION RFD is intended for use in providing medical imaging, using pulsed and continuous fluoroscopic digital imaging, as well as digital subtraction and cine image capture during diagnostic interventional and surgical procedures where intra-operative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional angiography, electrophysiology, pediatrics, endoscopic, urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room procedures, and those procedures visualizing structures of the cervical, thoracic, and lumber regions of the spine and joint fractures of the upper and lower extremities, and where digital image data is required for computer aided surgery procedures, and whenever the clinician benefits from the high degree of geometric imaging accuracy, and where such fluoroscopic, cine and DSA imaging is required in and around high magnetic fields. The visualization of such anatomical structures assists the clinician in the clinical outcome. At the discretion of a physician, the device may be used for other imaging applications.

This device does not support direct radiographic film exposures and is not intended for use in performing mammography. The system is not intended for use near MRI systems.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K132904